

## **REMARKS**

The Office Action mailed March 2, 2010 (hereinafter, “Office Action”) has been reviewed and the Examiner’s comments considered. Claims 1-19 and 21-22 are currently pending. No amendments are presented herein.

### **Response to Arguments**

In the Response filed January 11, 2010, Applicant distinguished St. Germain from the pending claims by noting that neither the rapid exchange (RX) embodiment shown in FIG. 8, nor the over the wire (OTW) embodiment shown in FIGS. 6-7, showed each of the elements of independent claims 1, 19, and 21. In particular, Applicant pointed to the difference between St. Germain FIG. 8, showing a RX configuration with a proximal guidewire exit port, and St. Germain FIGS. 6-7, showing differently an OTW configuration with a guidewire lumen that extends to the proximal end of the device similar to the embodiments shown in FIGS. 1-5. Thus, Applicant concluded that a *prima facie* case of anticipation could not be established because the OTW configuration of FIGS. 6-7 failed to show at least a proximal guidewire exit port or a RX configuration, and because the RX configuration of FIG. 8 failed to show at least a pusher tube as claimed. Further, Applicant noted that the embodiments of FIGS. 6-7 and FIG. 8 could not be combined without substantial reconstruction and redesign of the St. Germain catheter.

In the Office Action Response to Arguments section, the Examiner finds the Applicant’s arguments unpersuasive for the stated reasons that: 1) the second shaft element was misnumbered and should have been reference number 15, and 2) the proximal guidewire exit port, as claimed, is shown in port 130 of St. Germain.

In view of the Examiner’s response, it does not appear that the Applicant’s arguments were fully considered. Accordingly, Applicant requests favorable reconsideration in view of the further clarification herein.

In reply to the Examiner's stated reasons, Applicant submits that: 1) regardless of whether the claimed second shaft element is identified in St. Germain as 155 or 15, neither the OTW or RX configuration of St. Germain show both a proximal guidewire exit port and a pusher tube, as claimed, and 2) the proximal guidewire exit port cannot be found in St. Germain reference number 130, because St. Germain shows and describes this feature as a "hydrating luer 130, which is preferably located on the distal end of the manifold 100 and is used to purge air from the catheter."

In support of Applicant's arguments above, which are repeated from the previous Response filed January 11, 2010, Applicant notes that the OTW embodiment of FIGS. 6-7 is introduced as an "alternative embodiment" just as the OTW embodiments of FIGS. 1-5 are introduced. Differently, the RX embodiment of FIG. 8 is introduced as "a rapid exchange embodiment." A side-by-side comparison of FIG. 6 and FIG. 8 reveals that the location of the proximal guidewire exit port, were it to be included in FIG. 6, would be shown in the representative drawing (but is not). Moreover, in FIG. 6 the catheter 155, which includes the guidewire lumen 15 and pull back lumen 150, replaces the outer sheath of FIG. 8. St. Germain describes pull back lumen 150 as being "axially connected to the guide wire lumen, traveling along the length of the guide wire lumen 15 up to the distal tip 25." (St. Germain, col. 6:8-12.)

### **Claim Rejections - 35 U.S.C. § 102**

Claims 1-3, 5-8, 10-15, and 19-22 stand rejected under 35 U.S.C. 102(b) as being anticipated by USPN 5,534,007 to St. Germain et al. (hereinafter, "St. Germain"). Applicant respectfully traverses this rejection.

In view of the above, Applicant submits that St. Germain does not anticipate independent claims 1, 19, or 21, or claims 2-3, 5-8, 10-15, or 22 depending therefrom, and therefore requests favorable reconsideration and withdrawal of the rejection under 35 U.S.C. § 102. Applicant notes that claim 20 has been canceled, and therefore the rejection of claim 20 is moot.

### **Claim Rejections - 35 U.S.C. § 103**

Claims 4, 9, and 16 stand rejected under 35 U.S.C. 103(a) as being unpatentable over St. Germain. Claims 17-18 stand rejected under 35 U.S.C. 103(a) as being unpatentable over St. Germain in view of USPN 6,514,196 to Sullivan et al. Applicant respectfully traverses these rejections.

In the Response filed January 11, 2010, Applicant commented specifically on claims 4 and 9. However, the Examiner did not respond to either argument in the Response to Arguments section of the Office Action. Accordingly, the arguments are reproduced below, and Applicant respectfully requests consideration thereof.

Regarding claim 4, the Office Action states that it would have been obvious to have an outer puller ring because “it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art.” (Office Action, p. 4.) However, the outer pull ring of claim 4 is not a *duplication* of the inner pull ring, but rather works in conjunction to compress the sheath therebetween. In other words, the outer pull ring is a distinct feature from the inner pull ring, rather than merely a second inner pull ring as the Office Action appears to allege.

Regarding claim 9, the Office Action states that it would have been obvious to keep a pusher tube and pusher guide tube separate, and further that parts 140, 60, or 25 are capable of acting as an adaptor block. However, with reference to the discussion above in connection with independent claim 1, the RX embodiment of St. Germain FIG. 8 does not show a pusher tube. Moreover, contrary to the assertion in the Office Action, parts 140 (annular collar), 60 (stopper), and 25 (distal tip) are not capable of acting as the claimed adapter block at least because none have the requisite structure, including “two lumens side-by-side, one for the pusher tube and the other for the pusher-guider tube.”

Applicant submits that a *prima facie* case of obviousness is not established with respect to these independent claims at least because not all of the features are shown or described by the

cited art. Further, each of rejected claims 4, 9, and 16-18 depend from patentable independent claim 1, in view of the above, and are therefore patentable for this reason. Accordingly, without conceding the allegations in the Office Action or the propriety of the asserted combination of references, Applicant respectfully requests favorable reconsideration and withdrawal of the rejections under 35 U.S.C. § 103.

### **Conclusion**

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejections of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

It is noted that the remarks herein do not constitute, nor are they intended to be, an exhaustive enumeration of the distinctions between the cited references and the claimed invention. Rather, the distinctions identified and discussed herein are presented solely by way of example. Consistent with the foregoing, the discussion herein should not be construed to prejudice or foreclose future consideration by Applicant of additional or alternative distinctions between the claims of the present application and the references cited by the Examiner and/or the merits of additional or alternative arguments.

Application No. 10/580,200  
Amendment dated June 1, 2010  
Reply to Office Action of March 2, 2010

Docket No.: 568-PDD-03-14-US-[43P]

Applicant believes no fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 50-2191, under Docket No. 101671.0043P from which the undersigned is authorized to draw.

Dated: June 1, 2010

Respectfully submitted,

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